

### **REMARKS**

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections, in light of the foregoing amendments and following remarks.

#### **Status of Claims**

Claims 14, 21-22, 24 and 33 have been withdrawn from consideration by the Office.

Applicants believe that withdrawal of Claim 14 from consideration by the Office was in error and request re-instatement of Claim 14.

Claims 21-24 and 33 have been canceled.

Claim 1 has been amended.

Claims 1-20 and 25-32 are pending for the Examiner's consideration.

For the reasons that follow, Applicants believe all Claims are now in condition for allowance.

#### **Amendments of Claims**

In compliance with the final restriction requirement and in order to expedite prosecution of the present application, Claim 1 has been amended and Claims 21-22, 24 and 33 have been canceled as being drawn to a nonelected invention. Claim 23 has been canceled as directed to the subject matter, which is identical to the subject matter of Claim 1. Neither cancellation of Claims 21-24 and 33, nor amendment of Claim 1 constitutes any admission regarding the subject matter. Applicants reserve a right to pursue this subject matter in this or other application(s).

Applicants have further amended Claim 1 to correct the claim language in regard to the omissions caused by clerical or typographical errors. Specifically, the recitations "X is NH" and "X<sub>2</sub> is H" have been added. Support for this amendment can be found, for example, in Example 9, which teaches 2,3-difluoro-6-[1,3,4]oxadiazol-2-yl-phenyl)-(4-iodo-2-methyl-phenyl)-amine, the species elected in the Response to October 3, 2003 Office Action.

No new matter was added by way of these amendments. The Examiner is hereby requested to enter these amendments.

#### **Obviousness-Type Double Patenting Rejection**

Claims 1-13, 15-20, 23 and 25-32 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 22-42 of U.S. Patent No. 6,545,030 ('030 patent). The rejection is traversed for the reasons set forth below.

Unlike the claims of the '030 patent, which are directed to a method of treating a proliferative disease, cancer, stroke, heart failure, reducing the symptoms of xenograft rejection, arthritis, cystic fibrosis, hepatomegaly, cardiomegaly, Alzheimer's disease, complication of diabetes, septic shock or viral infection, the claims of the instant invention are directed to treating chronic pain. Given the well-established unpredictability in the art of physiological activity (*In re*

*Fisher* 166 USPQ 18, 24 (CCPA 1970)), the instant claims are not an obvious variation of the invention claimed in the '030 patent. Accordingly, Applicant respectfully requests withdrawal of this rejection.

**Rejection under 35 U.S.C. § 102(e)**

Claims 1-13, 15-20, 23 and 25-32 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,545,030 ('030 patent). The rejection is traversed for the reasons set forth below.

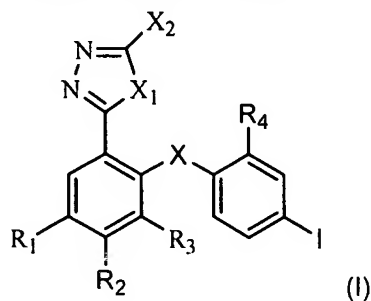
Applicants contend that "...for anticipation under 35 U.S.C. § 102, the reference must teach each and every aspect of the invention either explicitly or impliedly. Any feature not directly taught must be inherently present." MPEP 706.02.

Unlike the '030 patent, which teaches a method of treating a proliferative disease, cancer, stroke, heart failure, reducing the symptoms of xenograft rejection, arthritis, cystic fibrosis, hepatomegaly, cardiomegaly, Alzheimer's disease, complication of diabetes, septic shock or viral infection, the instant invention is directed to treating chronic pain. Furthermore, given the well-established unpredictability in the art of physiological activity (*In re Fisher* 166 USPQ 18, 24 (CCPA 1970)), the claimed methods of the present invention are not inherently present in the disclosure of the '030 patent. Accordingly, Applicant respectfully requests withdrawal of this rejection.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1-13, 15-20, 23 and 25-32 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Boschelli et al. U.S. Patent No. 5,462,952 ('952 patent) for the reasons set forth on page 4-6 of the Office Action. The rejection is traversed for the following reasons.

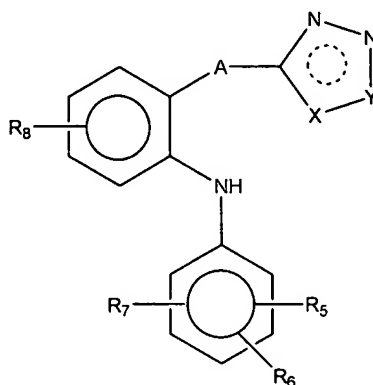
The present invention is directed to a method for treating chronic pain, said method comprising administering to a subject in need of such treatment a composition comprising a MEK inhibitor selected from a compound of formula (I):



Thus, to establish a prima facie case of obviousness, the Examiner must show: (1) some suggestion or motivation for one of ordinary skill in the art to modify reference teachings in a way that would provide a method for treating chronic pain, which method comprises administering to a subject in need of such treatment a composition comprising a MEK inhibitor selected from a compound of formula (I); and (2) a reasonable expectation of success that administering to a

subject such a composition comprising a MEK inhibitor selected from a compound of formula (I) will provide a method for treating chronic pain. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and must not be based on the applicant's disclosure. Finally, the prior art reference must teach or suggest all claim limitations. *in re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Danco*, 160 F.3d 1339 (Fed. Cir. 1998); M.P.E.P. 2143.

The '952 patent teaches 1,3,4-thiadiazoles and 1,3,4-oxadiazoles having activity as inhibitors of singly or together 5-lipoxygenase and cyclooxygenase defined by Formula:



Nowhere the '952 patent discloses the employment of the particular MEK inhibitors in methods of treating chronic pain. Although the compounds of formula I are a sub-genus of the genus disclosed in the '952 patent, wherein A is a bond; X is O or S; Y is C-SR<sub>1</sub>, C-NR<sub>1</sub>R<sub>3</sub>, COR<sub>1</sub>; R<sub>6</sub> is iodine, the Office Action did not establish how one of ordinary skill in the relevant art would have been motivated to select the species or subgenus from the disclosed prior art genus to arrive at MEK inhibitors administering to a subject for treating chronic pain as claimed by the methods of the present invention. Thus, the Office Action did not establish a *prima facie* case of obviousness in the present situation.

Applicants respectfully request that the rejection under § 103 over Boschelli et al. U.S. Patent No. 5,462,952 be withdrawn.

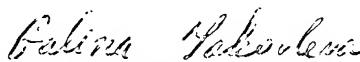
**Conclusion**

Applicants believe all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiners satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

Applicants do not believe any fees are due in connection with this response. If any fees are due in connection with this response, please charge such fees to Deposit Account No. 500329.

Respectfully submitted,

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